EXHIBIT I

ETHICON, INC.
a Johnson & Johnson company

Document Name (#): RMP-0000001
Revision: 01

RISK MANAGEMENT PLAN
ETHICON, INC. – LEGACY DEVICES

Revision History

Revision # *(Insert the Rev # in ascending order)*	Summary of Change *(Describe the change, and the section of the form where the change occurred.)*	Originator *(Insert the author of the document or change)*
1	New document	M. Viscido

Obsolete MV 5/30/2008

Originator:

Print Name: Michael Viscido /Sign: Michael Viscido 7/17/2007

Approval:

WW Risk Management & Quality Engineering:

Print Name: MARK YOUR /Sign: 18 July 2007

Regulatory Affairs:

Print Name: Jennifer M. Paine /Sign: Jennifer Paine 19 Jul 07

Overall Legacy Device Risk Management Strategy:

Legacy device risk management (RM) activities will be handled as follows:

1. All legacy devices will follow the risk management plan as described by this document.
2. All legacy devices will be prioritized in a priority matrix (FM-0000861) and then addressed accordingly. Risk management activities for all legacy products covered by this plan will be completed in accordance to a separate project timeline.
3. In certain cases devices will be grouped into categories and covered in a single risk management report. These groupings will be explained in the risk management report. If the device is unique by nature it will be handled separately.
4. The output of each product category (or unique device, if applicable) RM process will be a risk management report and any appropriate supporting documents.
5. *EXCEPTIONS*:
    a. When the risk management process is triggered by a product change that does not require design validation or is not due to the occurrence of an unanticipated critical failure mode this Legacy Risk Management Process is not required. The Quality Engineer responsible for the risk management portion of the project must provide the appropriate level of documented review and rationale required to address the project needs.
    b. The WW Director Risk Management/Quality Engineering (or authorized delegate) in a memo providing appropriate rationale filed with Risk Management documentation for the specific product/product category involved can authorize exceptions/deviations to this plan.

Product Scope:

The entire life cycle of the product must be considered when implementing this risk management process.

Products covered by this document (description):

All products defined as "Legacy Devices" in PR602-003, Company Procedure for Medical Device Risk Management Plan (shown below).

Legacy Devices: Devices released under a risk management program that pre-dates version/revision 7 of PR602-003

OR

Legacy devices are those medical devices that have not undergone ISO 14971 compliant risk management activities that are required to have such

review either by regulatory and/or other business requirement (e.g. local procedure, new safety related information, etc.).

Product code numbers & Manufacturing locations:

The specific product code & manufacturing information will be provided in the Risk Management Report for each product/product category.

Product Category/Product Description/Identification:

Where appropriate consult specific product/product category RM Reports for product description information.

Plan Prepared by:

M. Viscido

Description of changes from last revision:

N/A

Reference Documents (As Applicable):

1) PR602-003, Company Procedure for Medical Device Risk Management Plan
2) PT-0005674, Risk Management Protocol: Ethicon, Inc. – Process for Legacy Devices
3) FM-0000861, North America Legacy Product Prioritization Matrix
4) PR-0000277, Company Procedure For Evaluation of Clinical Data For CE-Marking

Verification of Activities

Completion and approval of the risk management report will serve as evidence to verify that all significant risks have been identified and are acceptable.

Responsibilities

Title	Responsibility
Sr. Project Manager, Product Risk	Responsible for creating, implementing, managing and distributing the plan.
WW Director, Risk Management & Quality Engineering	Responsible for approving the risk management plan and ensuring adequate resources are available to implement the plan.
Director or Manager, Regulatory Affairs	Responsible for approving the risk management plan.

Schedule to Review Plan

This plan will be reviewed annually at a minimum. The review will be documented and placed with the original version of this plan in the WW Risk Management departmental files. Updates to the priority matrix only are not required to be documented and can be completed as needed (e.g. as updated priority elements become known).

The Sr. Project Manager, Product Risk, will communicate any revisions to the plan or priority matrix to the affected parties.

Criteria for Evaluating Risk

Risks will be evaluated utilizing criteria provide in this plan as set forth below and PR602-003.

Legacy Device Risk Management Process:

The following table outlines the steps for the RM process.

Step	Description	Comment
1	Obtain and review all applicable labeling (e.g. instruction for use, etc.) and any existing risk management documentation.	
2	Utilizing the information from step1, identify the hazards & related harms and place them in the Harms/Hazards Summary table.	This table is described in PR602-003, Step 2.
3	Obtain and review the latest literature review and summary report or clinical expert report for the product/product category being examined for any additional hazard or harm not yet described from another source and add to the Harm(s)/Hazard(s) summary table. [1] OR Conduct a literature review in accordance with PR-0000277, sect. 6.3.2, for any additional hazard or harm not yet described from another source and add to the Harm(s)/Hazard(s) summary table.	To utilize existing reviews they can only be 5 years old or less. This timeframe can be adjusted downward (& documented) based on the opinion of the medical/clinical expert involved in the review.
4	Reviews the previous 2 years of related category/product complaint data for any additional hazard or harm not yet described from another source and add to the Harm(s)/Hazard(s) summary table.	Includes MDRs/MDVs
5	Obtain the appropriate manufacturing information* for the previous 2 years to use in conjunction with the	*Manufacturing information means units sold or units

[1] Person(s) suitably qualified in the relevant field, knowledgeable in the "state of the art" and able to demonstrate objectivity must perform Literature Review and Clinical Expert Reporting.

Step	Description	Comment
	information in steps 2 & 3 to determine the probability of occurrence of each identified harm. (Where quantitative probability estimation is not possible based on available data, qualitative description should be utilized.)	manufactured depending on available data.
6	For each identified hazard the need for risk reduction should be evaluated and if required completed as described in PR602-003	Risk reduction is required when the Severity of the Harm is rated 9 or 10 AND the Rank of Frequency is "Low" or greater (as defined in PR602-003)
7	After all risk control measures have been completed the Overall Residual Risk must be assessed per PR602-003.	NOTE: A search of publicly available information if Overall Residual Risk (ORR) is rated "Moderate" or "High" (as described in PR602-003 must also be undertaken at his stage to ensure the ORR is appropriate and that unnecessary additional risk is avoided.
8	Complete the Risk Management Report and place all appropriate Risk Management documentation into the correct file per PR602-003.	Generally risk documentation is filed with the eDHF (or equivalent file) if available, otherwise it is placed in the WW Risk Management files
9	Ensure the Product/Product Category has been placed in the Post-Market Surveillance process that is currently done for all existing legacy devices (e.g. complaint monitoring and trending)	